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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,828	08/28/2003	Sergei Zolotukhin	5853-251	9126
7590 12/01/2005 Akerman Senterfitt Suite 400 222 Lakeview Avenue West Palm Beach, FL 33402-3188			EXAMINER GUZO, DAVID	
			ART UNIT 1636	PAPER NUMBER

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/651,828

Applicant(s)

ZOLOTUKHIN, SERGEI

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) 58-78 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-34 and 51-57 is/are allowed.
- 6) ☒ Claim(s) 1,4-18 and 35-50 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/10/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **Detailed Action**

Applicant's election without traverse of Group I, Claims 1-57 in the reply filed on 9/9/05 is acknowledged.

Claims 58-78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/9/05.

### **35 USC 102 Rejections**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-9, 12-13, 16-18, 35-40 and 43-50 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by During et al.

Applicants claim a non-naturally occurring nucleic acid (which can be in a vector) comprising: (A) a first nucleotide sequence encoding at least one AAV Rep protein (which can be from a AAV2 serotype); and (B) a second nucleotide sequence encoding at least one AAV Cap protein wherein the second nucleotide sequence comprises (i) a polynucleotide encoding a portion of a Cap protein found in an AAV of a first serotype

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(which can be an of AAV1-8 serotypes) but not in an AAV of a second serotype differing from the first serotype and (ii) a polynucleotide encoding a portion of a Cap protein found in the AAV of the second serotype, but not in the AAV of the first serotype.

Applicants also claim a vector library comprising at least two vectors wherein the first vector comprises a nucleic acid as described above and a second vector differing from the first vector by at least one nucleotide, wherein said vector library is incorporated into a insect cell. Applicants also claim a AAV virion (which can be in a host human cell) comprising a nucleic acid comprising: a first AAV TR, a second AAV TR and a non-AAV nucleic acid (which can be a sequence encoding a therapeutic protein wherein the sequence is operably linked to a promoter which can be tissue specific) interposed between the first AAV TR and second AAV TR; and at least one AAV Cap protein, wherein the Cap protein is encoded by a nucleotide sequence comprising nucleic acid sequences from AAVs of at least a first serotype and a second serotype differing from the first serotype.

During et al. (US 2002/0045264, published 4/18/2002, filed 3/13/2001, priority to 3/14/2000, see whole document, particularly paragraphs [0014], [0022], [0059]-[0065], [0067]-[0068], [0090], [0095], [0099]-[0100] and Claims 1-49) teaches the generation of recombinant AAV virions comprising chimeric cap proteins generated by a nucleic acid construct comprising sequences encoding a rep gene (which can be from AAV2) from any AAV serotype and sequences encoding different portions of one or more cap genes from one or more AAV serotypes (which can be from any or all of AAV1-6 serotypes) so as to redirect the tropisms of AAV vectors. During et al. also teaches a vector library

comprising a first vector encoding the AAV rep and chimeric cap genes and a second AAV vector comprising AAV ITRs (TRs) flanking a promoter (which can be tissue specific) and a transgene (which can encode a therapeutic protein) wherein the vector library can be introduced into insect cells. The vector system described by During et al. is designed to package recombinant AAV vectors comprising a transgene operably linked to a promoter of interest into AAV virions comprising chimeric cap proteins and introduce said virions into animal (human) cells so as to express the transgene. During et al. therefore teaches the claimed invention.

Claims 1, 4-18 and 35-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Gao et al.

Applicants' invention is as described above. In addition applicants recite a non-naturally occurring nucleic acid comprising sequences encoding a chimeric AAV capsid comprising a portion of a AAV7 or AAV8 serotype capsid and a portion of a second capsid gene not found in said AAV7 or AAV8 serotype and AAV virions comprising unique sequences from up to eight different AAV serotypes. Additionally, applicants recite that the nucleic acid comprising the rep and cap gene sequences also contains a sequence encoding a helper function which may be from an adenovirus.

Gao et al. (US 2003/0138772, published 7/24/2003, priority to 11/13/2001, see whole document, particularly paragraphs [0024], [0091], [0107], [0110], [0111], [0118], [0122], [0133], [0154] and [0249]) teaches the generation of recombinant AAV virions comprising chimeric cap proteins generated by a nucleic acid construct comprising

sequences encoding a rep gene (which can be from AAV2) from any AAV serotype and sequences encoding different portions of one or more cap genes from one or more AAV serotypes (which can be from any or all of AAV1-8 serotypes) so as to redirect the tropisms of AAV vectors. Gao et al. also teaches a vector library comprising a first vector encoding the AAV rep and chimeric cap genes and a second AAV vector comprising AAV ITRs (TRs) flanking a promoter (which can be tissue specific) and a transgene (which can encode a therapeutic protein) wherein the vector library can be introduced into insect cells. The vector system described by Gao et al. is designed to package recombinant AAV vectors comprising a transgene operably linked to a promoter of interest into AAV virions comprising chimeric cap proteins and introduce said virions into animal (human) cells so as to express the transgene. Gao et al. therefore teaches the claimed invention.

Claims 19-34 and 51-57 are free of the prior art because said art does not teach or suggest AAV virions (or virion libraries) comprising AAV ITRs (TRs) flanking packaging sequences comprising the rep gene and sequences encoding chimeric capsid proteins. The prior art teaches transfer vectors comprising AAV ITRs flanking the transgene because the sequence encoding the transgene is what is desired to be packaged into the recombinant AAV virion and to be delivered to the target cell, not the sequences encoding the helper rep and chimeric capsid functions.

Claims 2-3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Claims 19-34, 51-57 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
November 18, 2005

  
DAVID GUZO  
PRIMARY EXAMINER